

the envelopes containing the articles bore no labeling containing directions for use; and, Section 502 (f) (2), they bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

It was charged also that the defendant's acts resulted in the misbranding of the *seconal sodium capsules* under Section 502 (d), in that the capsules contained in the envelopes contained a chemical derivative of barbituric acid, seconal, which derivative had been found, and by regulations designated as, habit forming; and the label of the article in the envelopes failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: On October 9, 1946, the defendant having entered a plea of not guilty, the case came on for trial before the court. At the conclusion of the trial, the court handed down a verdict of not guilty.

2054. Misbranding of diethylstilbestrol tablets, elixir alurate, and ephedrine and amytal pulvules. U. S. v. Louis L. Patt (Courtesy Drug Store) and Al Defnet. Pleas of nolo contendere. Fine of \$200 against Louis L. Patt on count 1. Imposition of sentence against Louis L. Patt suspended on counts 2 and 3; sentence against Al Defnet suspended on all counts. Both defendants placed on probation for 1 year. (F. D. C. No. 20118. Sample Nos. 73926-F, 73934-F, 73975-F.)

INFORMATION FILED: April 24, 1946, District of Arizona, against Louis L. Patt, trading as the Courtesy Drug Store, Phoenix, Ariz., and Al Defnet, an employee.

INTERSTATE SHIPMENT: Between the approximate dates of May 29, 1944, and September 27, 1944, from Philadelphia, Pa., Nutley, N. J., and Indianapolis, Ind., of quantities of *diethylstilbestrol tablets*, *elixir alurate*, and (capsules) *ephedrine and amytal pulvules*.

PRODUCT: The drugs had been made for use exclusively by or on the prescription of a physician, and the labels bore the statement, "Caution: To be used only by or on the prescription of a physician." As a result the drugs were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling.

LABEL, WHEN SHIPPED: "Diethylstilbestrol * * * Warning: This is a potent drug and serious consequences may result if used other than under constant medical supervision"; "Elixir Alurate * * * contains ½ gr. Allyl-Isopropyl-Barbituric Acid Warning: May Be Habit Forming"; or "Pulvules Ephedrine and Amytal Warning: May Be Habit Forming."

NATURE OF CHARGE: *Diethylstilbestrol tablets* and *elixir alurate*. On or about September 30 and October 13, 1944, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused them to be sold, delivering them to the purchasers in the bottles labeled as indicated above, without a physician's prescription. The sale of the drugs by the defendants caused the exemption to expire and resulted in the misbranding of the drugs in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

Ephedrine and amytal pulvules. On or About November 22, 1944, the defendants removed a number of pulvules (capsules) from the bottle and repacked them into an unlabeled cardboard box and sold them without a prescription. The acts of the defendants resulted in the drug being misbranded in violation of Section 502 (f) (1), since the cardboard box bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the drug failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users.

DISPOSITION: On May 13, 1946, the defendant, Louis L. Patt, having entered a plea of nolo contendere, the court imposed a fine of \$200 on count 1, suspended imposition of sentence against him on counts 2 and 3 for 1 year, and placed him on probation for that period of time. On June 3, 1946, Al Defnet, having entered a plea of nolo contendere, imposition of sentence against him was suspended on all counts for 1 year, and he was placed on probation for that period.